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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,573	04/02/2004	Steven L. Stice	60141.0003USC5	3805

7590 05/24/2006

Attention of Joseph Bennett-Paris, Ph.D.
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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,573	STICE ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/2/04; 2/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The preliminary amendment received April 2, 2004 has been entered. Claim 1 is pending.

The IDS filed April 2, 2004 is improper. It contains several PTO-892's and PTO-1449's from parent applications. These are improper as there is no place for the examiner to initial or sign. If applicant wishes these references to be considered and made of record, applicant needs to comply with 37 § CFR 1.98. See MPEP 609.02 A2.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,945,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claim and those in '577 are of overlapping, obvious subject matter.

Present claim 1 is drawn to a method of cloning a pig comprising inserting a desired differentiated pig cell or cell nucleus into an enucleated pig oocyte under

conditions suitable for the formation of a nuclear transfer unit, activating the resultant nuclear transfer unit and transferring said cultured nuclear transfer unit to a host mammal such that the nuclear transfer unit develops into a fetus. The present specification defines the differentiated cell as being a proliferating somatic cell expanded in culture, donor cell being from mesoderm, endoderm or ectoderm, the donor cell being a fibroblast, the donor cell being from a fetus or and adult, the donor cell being an epithelial cell, neural cell, epidermal cell, keratinocyte, hematopoietic cell, melanocyte, chondrocyte, B-lymphocyte, T-lymphocyte, erythrocyte, macrophage, Monocyte or muscle, and the donor cells being from skin, lung, pancreas, liver, stomach, intestine, heart, reproductive organ, bladder, kidney or urethra. The present specification also defines the oocyte to be in vitro or in vivo matured prior to enucleation, where enucleation is by micro-surgical methods, and where enucleation is about 10 to 40 hours after initiation of in vitro maturation.

Claims 1-22 of '577 are to methods of cloning a nonhuman mammal by nuclear transfer comprising the introduction of a nonhuman mammalian donor cell or nucleus into a nonhuman mammalian enucleated oocyte of the same species, activating the nuclear transfer unit, implanting into the uterus of a surrogate mother of said species and permitting the nuclear transfer unit to develop into the cloned mammal, wherein he donor cell or nucleus is a proliferating somatic cell that has been expanded in vitro. Claim 13 specifically states porcine, which is a type ungulate as in claim 12. The claims of '577 state the differentiated cell as being a proliferating somatic cell expanded in culture, donor cell being from mesoderm, endoderm or ectoderm, the donor cell being a fibroblast, the donor cell being from a fetus or and adult, the donor cell being an epithelial cell, neural cell, epidermal cell, keratinocyte, hematopoietic cell, melanocyte, chondrocyte, B-lymphocyte, T-lymphocyte, erythrocyte, macrophage, monocyte or muscle, and the donor cells being from skin,

lung, pancreas, liver, stomach, intestine, heart, reproductive organ, bladder, kidney or urethra. The claims of '577 state the oocyte to be in vitro or in vivo matured prior to enucleation, where enucleation is by micro-surgical methods, and where enucleation is about 10 to 40 hours after initiation of in vitro maturation.

Therefore, present claim 1 contains all the limitations of claims 1-22 of '577. Thus at the time of the present invention, it would have been obvious for the ordinary artisan to arrive at the claimed invention given claims 1-22 of '577.

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 and 19-23 of U.S. Patent No. 6,215,041. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claim and those in '041 are of overlapping, obvious subject matter.

Present claim 1 is drawn to a method of cloning a pig comprising inserting a desired differentiated pig cell or cell nucleus into an enucleated pig oocyte under conditions suitable for the formation of a nuclear transfer unit, activating the resultant nuclear transfer unit and transferring said cultured nuclear transfer unit to a host mammal such that the nuclear transfer unit develops into a fetus. The present specification defines the differentiated cell as being a proliferating somatic cell expanded in culture, which is a non-quiescent cell, the donor cell being from mesoderm, endoderm or ectoderm, the donor cell being a fibroblast, the donor cell being from a fetus or and adult, the donor cell being an epithelial cell, neural cell, epidermal cell, keratinocyte, hematopoietic cell, melanocyte, chondrocyte, B-lymphocyte, T-lymphocyte, erythrocyte, macrophage, Monocyte or muscle, and the donor cells being from skin, lung, pancreas, liver, stomach, intestine, heart, reproductive organ, bladder, kidney or urethra. The present specification also defines the oocyte to be in vitro or in vivo matured prior to enucleation, where enucleation is

by micro-surgical methods, and where enucleation is about 10 to 40 hours after initiation of in vitro maturation. Further, the present specification defines the method of nuclear transfer as including culturing the activated nuclear transfer unit to greater than the 2-cell developing stage prior to transfer to a host pig and development into a cloned pig or pig fetus.

Claims 1-17 and 19-23 of '041 are drawn to methods of cloning a nonhuman mammal by nuclear transfer comprising the introduction of a non-quiescent nonhuman mammalian donor cell into a nonhuman mammalian enucleated oocyte of the same species as the donor cell to form a nuclear transfer unit, implantation of the nuclear transfer unit into the uterus of a surrogate mother of said species and permitting the development of the nuclear transfer unit into a cloned mammal. Claim 8 specifically states porcine. The claims of '041 defines the differentiated cell as being a proliferating somatic cell expanded in culture, which is a non-quiescent cell, the donor cell being from mesoderm, endoderm or ectoderm, the donor cell being a fibroblast, the donor cell being from a fetus or and adult, the donor cell being an epithelial cell, neural cell, epidermal cell, keratinocyte, hematopoietic cell, melanocyte, chondrocyte, B-lymphocyte, T-lymphocyte, erythrocyte, macrophage, monocyte or muscle, and the donor cells being from skin, lung, pancreas, liver, stomach, intestine, heart, reproductive organ, bladder, kidney or urethra. The claims of '041 state the oocyte to be in vitro or in vivo matured prior to enucleation, where enucleation is by micro-surgical methods, and where enucleation is about 10 to 40 hours after initiation of in vitro maturation. The claims of '041 state the nuclear transfer unit is cultured to the 2-cell developmental stage prior to transfer to a host for development.

Therefore, present claim 1 contains all the limitations of claims 1-17 and 19-23 of '041. Thus at the time of the present invention, it would have been obvious for

the ordinary artisan to arrive at the claimed invention given claims 1-17 and 19-23 of '041.

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,235,969. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claim and those in '969 are of overlapping, obvious subject matter.

Present claim 1 is drawn to a method of cloning a pig comprising inserting a desired differentiated pig cell or cell nucleus into an enucleated pig oocyte under conditions suitable for the formation of a nuclear transfer unit, activating the resultant nuclear transfer unit and transferring said cultured nuclear transfer unit to a host mammal such that the nuclear transfer unit develops into a fetus. The present specification defines the differentiated cell as being a proliferating somatic cell expanded in culture, which is a non-quiescent cell, the donor cell being from mesoderm, endoderm or ectoderm, the donor cell being a fibroblast, the donor cell being from a fetus or and adult, the donor cell being an epithelial cell, neural cell, epidermal cell, keratinocyte, hematopoietic cell, melanocyte, chondrocyte, B-lymphocyte, T-lymphocyte, erythrocyte, macrophage, Monocyte or muscle, and the donor cells being from skin, lung, pancreas, liver, stomach, intestine, heart, reproductive organ, bladder, kidney or urethra. Further, the present specification defines the method of nuclear transfer as including culturing the activated nuclear transfer unit to greater than the 2-cell developing stage prior to transfer to a host pig and development into a cloned pig or pig fetus. The differentiated cell is defined as being genetically modified.

Claims 1-26 of '969 are drawn to methods of cloning a pig comprising inserting a non-quiescent differentiated pig cell or nucleus into an enucleated pig

oocyte under conditions suitable for the formation of nuclear transfer unit, activating the nuclear transfer unit and transferring the activated nuclear transfer unit to a host pig such that the nuclear transfer unit develops into a fetus. The claims in '969 state the fetus is allowed to develop into a pig, the differentiated pig cell is genetically modified, the fetus develops into an offspring, and the nuclear transfer unit is cultured to the greater that 2-cell developmental stage. The claims in '969 state differentiated cell as being a proliferating somatic cell expanded in culture, which is a non-quiescent cell, the donor cell being from mesoderm, endoderm or ectoderm, the donor cell being a fibroblast, the donor cell being from a fetus or and adult, the donor cell being an epithelial cell, neural cell, epidermal cell, keratinocyte, hematopoietic cell, melanocyte, chondrocyte, B-lymphocyte, T-lymphocyte, erythrocyte, macrophage, Monocyte or muscle, and the donor cells being from skin, lung, pancreas, liver, stomach, intestine, heart, reproductive organ, bladder, kidney or urethra. The claims further states the oocyte is matured prior to enucleation, activation is by exposure to two or one electrical pulses, activation is by exposure to at least one activating factor isolated from sperm cells. Also, the claims state a cell of the nuclear transfer unit is combined with an embryo to produce a chimeric embryo, which is then transferred to a host pig such that the chimeric embryo develops into a chimeric fetus or offspring, and that the donor cell is non-quiescent differentiated pig CICM cell. Claims 24-26 are to a method of producing a nonhuman mammalian embryo by nuclear transfer comprising transplantation of a nonhuman mammalian cell into an enucleated oocyte of the same species as the donor cell, activating the recipient oocyte and incubation to produce an embryo, the embryo being a porcine or ungulate embryo.

Therefore, present claim 1 contains all the limitations of claims 1-26 of '969. Thus at the time of the present invention, it would have been obvious for the ordinary artisan to arrive at the claimed invention given claims 1-26 of '969.

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-21 of U.S. Patent No. 6,235,970. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claim and those in '970 are of overlapping, obvious subject matter.

Present claim 1 is drawn to a method of cloning a pig comprising inserting a desired differentiated pig cell or cell nucleus into an enucleated pig oocyte under conditions suitable for the formation of a nuclear transfer unit, activating the resultant nuclear transfer unit and transferring said cultured nuclear transfer unit to a host mammal such that the nuclear transfer unit develops into a fetus.

Claims 19-21 of '970 are to a method of producing a nonhuman mammalian embryo by nuclear transfer comprising transplantation of a nonhuman mammalian cell into an enucleated oocyte of the same species as the donor cell, activation of the recipient oocyte, and incubation of the activated oocyte to produce an embryo, wherein the donor cell is a proliferating mammalian differentiated cell. Claim 20 specifically states "pig," and claim 21 specifically states "ungulate," to which pig belongs. Further, the present specification defines the differentiated cell as being proliferating.

Therefore, present claim 1 contains all the limitations of claims 19-21 of '970. Thus at the time of the present invention, it would have been obvious for the ordinary artisan to arrive at the claimed invention given claims 19-21 of '970.

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 49 and 50 of copending

Application No. 09/394,902. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are of obvious, overlapping scope.

Present claim 1 is drawn to a method of cloning a pig comprising inserting a desired differentiated pig cell or cell nucleus into an enucleated pig oocyte under conditions suitable for the formation of a nuclear transfer unit, activating the resultant nuclear transfer unit and transferring said cultured nuclear transfer unit to a host mammal such that the nuclear transfer unit develops into a fetus.

Claims 49-50 are drawn to a method for cloning a porcine fetus or live offspring comprising activating a porcine oocyte, transferring a differentiated porcine cell or nucleus into said porcine oocyte, removing the endogenous oocyte nucleus if not already removed and transferring the nuclear transfer unit after an optional culturing step to female pig to produce a porcine fetus or offspring.

As the order of method steps is not limited to the order present in the claims unless so specified, present claim 1, therefore, contains all the limitations of claims 49 and 50 of '902. Thus at the time of the present invention, it would have been obvious for the ordinary artisan to arrive at the claimed invention given claims 49 and 50 of '902.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of cloning a pig comprising inserting

a desired differentiated pig cell or cell nucleus into an enucleated MII pig oocyte, under conditions suitable for the formation of a nuclear transfer unit, activating the resultant nuclear transfer unit, and synchronously transferring 20-30 of the cultured nuclear transfer units with a sufficient number of pig embryos to a host pig such that the nuclear transfer unit develops into a fetus, does not reasonably provide enablement for an enucleated oocyte at any stage of development or transferring the nuclear transfer unit alone. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification states "methods of embryo one cell embryo transfer in pigs are well known .... 20-30 NT units are synchronously transferred to the oviduct of bred or unbred gilts" (specification, page 53.) The guidance obtained from the specification is for 2-30 NT units to be transferred to recipient female pigs, and the NT units synchronized with the recipients. Further, the only guidance or discussion regarding oocyte developmental stage for the claimed method of cloning pigs is that the oocytes be in metaphase II (MII). This is true for oocytes matured in vivo or matured in vitro. In each case the specification only teaches the development of the oocytes to MII (specification, page 24, lines 13-19 and lines 24-26). The specification provides no guidance for other developmental stage oocytes for use in the claimed method. The specification further states MII oocytes are used in nuclear transfer methods because "it is believed that the oocyte can be or is sufficiently 'activated' to treat the introduced nucleus as it does fertilizing sperm" (specification, page 25, lines 9-14). Thus, at the time of filing, the ordinary artisan would have needed to conduct an undue amount of experimentation without a predictable degree of success to implement the invention as presently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 1 states "method of cloning a pig," but the body of the claims ends with the nuclear transfer unit developing into a fetus. Thus the metes and bounds of the claim isn't clear. Is the claim to cloning a pig or cloning a pig fetus?

Claim 1, (iii) states "transferring said cultured NT unit." However, there are no culturing steps in claim 1.

The claims are free of the prior art. At the time of filing, the prior art did not teach or suggest a method of cloning a pig comprising inserting a desired differentiated pig cell or cell nucleus into an enucleated pig oocyte under conditions suitable for the formation of a nuclear transfer unit, activating the resultant nuclear transfer unit and transferring said cultured nuclear transfer unit to a host mammal such that the nuclear transfer unit develops into a fetus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

May 16, 2006